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OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 12/14/2017

SUBJECT: Pymetrozine Acute, Chronic, and Cancer Dietary Exposure and Risk Assessments in Support of the Registration Review Risk Assessment

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Executive Summary

HED conducted acute, chronic, and cancer dietary (food and drinking water, drinking water only, and food only) exposure and risk assessments using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). The analyses were conducted in support of a draft human health risk assessment for registration review. This memorandum was reviewed by two peer reviewers of the DESAC, per DESAC Standard Operating Procedure (SOP) 2012.1.

Pymetrozine is registered for use on leafy vegetables (crop groups 4 and 5), fruiting vegetables, cucurbits, tuberous and corm vegetables, and a small number of individual crops. Tolerances have not been established for livestock commodities. HED incorporated the estimated drinking water concentrations (EDWCs) provided by the Environmental Fate and Effects Division (EFED) into the assessments. Pymetrozine is a carcinogen, and HED has assigned a cancer potency factor to it. The cancer risk estimates for drinking water alone, and for food plus drinking water are of concern when the cancer EDWC recommended by EFED is used. The cancer risk estimate for food only is not of concern; however, it is not significantly below the level of concern. The acute and chronic dietary risk estimates are also of concern for the most highly exposed population subgroups when drinking water is included in the assessments. Because of these risk issues, HED performed acute, chronic, and cancer dietary exposure assessments for food alone, drinking water alone, and food plus drinking water. For the acute and chronic assessments that included drinking water alone and food plus drinking water, HED used the EDWCs recommended by EFED. The EDWCs were derived using a total toxic residue approach, and include all degradates of concern in drinking water. The EDWCs were also based on the highest maximum label use rate. Because of risk estimates of concern, EFED provided HED with refined EDWCs based on alternate use rates (i.e., typical use rates rather than maximum use rates) or more restricted uses (i.e., use only on specific crops). HED performed cancer dietary exposure assessments using these refined EDWCs. The results of all of these assessments are reported in this dietary exposure memorandum.

Acute Dietary Exposure Assessment

The acute dietary exposure analyses are based on the assumption that all foods with pymetrozine tolerances bear maximum pymetrozine residues of concern, which include the parent and a number of plant metabolites. HED used conservative default processing factors for a small number of commodities. HED assumed 100% of all commodities with tolerances are treated. EFED determined that EDWCs resulting from groundwater from vulnerable wells are not expected to exceed 404 µg/L as the peak groundwater concentration. HED used this value to perform food only, drinking water only, and food plus drinking water assessments. For food only, the acute dietary risk estimates are not of concern. The general U.S. population uses 27% of the acute population adjusted dose (aPAD) at the 95th percentile of exposure. The most highly exposed population subgroup, Children 1-2 years old uses 45% of the aPAD. Acute dietary risks are of concern when residues in drinking water are included in the dietary exposure assessments. For the assessments that include drinking water only and food plus drinking water, the general U.S. population uses 270% and 290% of the aPAD, respectively. The most highly exposed population subgroup, All Infants, uses 850% of the aPAD for drinking water alone as well as for food plus drinking water.

Chronic Dietary Exposure Assessment

The chronic and cancer dietary exposure analyses are slightly more refined than the acute assessment in that average residue values from supervised crop field trials were used rather than maximum residues. As with the acute assessment, the residue values HED used include the parent and a number of plant metabolites. For most processed commodities, the residues used in the assessment accounted for concentration or reduction; however, conservative default

processing factors were used for a small number of commodities. Estimates of the actual percentage of the U.S. crop that is treated were used for several commodities. These commodities are ones that have high consumption. EFED determined that EDWCs resulting from groundwater from vulnerable wells are not expected to exceed 367 µg/L as the post-breakthrough average. HED used this value to perform food only, drinking water only, and food plus drinking water assessments. For food only, the chronic dietary risk estimates are not of concern. The general U.S. population and all population subgroups use <1% of the chronic population adjusted dose (cPAD). When residues in drinking water are included, chronic dietary risk estimates are of concern for some population subgroups, but not for others. The general U.S. population uses 95% of the cPAD when the assessments include drinking water only and food plus drinking water. The most highly exposed population subgroup, All Infants, uses 240% of the cPAD for drinking water alone as well as for food plus drinking water.

Cancer Dietary Exposure Assessment

The cancer dietary exposure assessment is based on the same refinements as the chronic assessment. HED determines cancer risk for the adult subpopulation with the highest exposure estimate. For pymetrozine, that subgroup is Adults 20-49 years old for all scenarios analyzed. HED used the cancer potency factor of $0.0119 \text{ (mg/kg/day)}^{-1}$ to determine cancer risk. Because the EDWCs resulted in cancer risk estimates of concern, HED requested that EFED provide refined EDWCs. The refined EDWCs are based on alternate use patterns or more restricted uses, and range from 20 ppb to 79 ppb. HED performed cancer dietary exposure assessments using these reduced EDWCs as well as the EDWC of 367 ppb for all uses. For the assessments that included food and drinking water, cancer risk estimates ranged from 5.7×10^{-6} (20 ppb EDWC) to 9.2×10^{-5} (367 ppb EDWC). For the assessments that included drinking water only, cancer risk estimates ranged from 5.0×10^{-6} (20 ppb EDWC) to 9.1×10^{-5} (367 ppb EDWC). For food only, the cancer risk estimate is 7.1×10^{-7} for Adults 20-49 years old.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose that HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population-adjusted dose (PAD). The PAD is equivalent to the point of departure (POD, NOAEL, LOAEL, e.g.) divided by the required uncertainty or safety factors.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. References that discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 21-JUN-2000, web link: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2007-0780-0001>; or see SOP 99.6 (20-AUG-1999).

The most recent dietary risk assessment for pymetrozine was conducted by C. Swartz (D372578, 4/2/2010).

II. Residue Information

Tolerances for pymetrozine are established in 40 CFR §180.556. The residue of concern for tolerance enforcement is parent pymetrozine. The residues of concern for risk assessment include parent pymetrozine as well as the following plant metabolites: GS-23199, CGA-215525, CGA-249257, and CGA-294849. The metabolite GS-23199 serves as a marker compound for CGA-215525, CGA-249257, and CGA-294849. As a result, the residue values used in the dietary analyses (acute, chronic, and cancer) include both parent and metabolites of potential risk concern. Residues of GS-23199 were reported in the available field trial data, and ratios based on metabolism studies were used to estimate residue levels for the remaining metabolites of concern (D310560, M. Doherty, 12/29/2004). The residue inputs for food commodities have not changed since the 2004 dietary assessment, and are provided in Attachment 1 along with the processing factors and the current percent crop treated estimates provided in the most recent SLUA. For the acute analysis, maximum residues of parent plus metabolites were used, and for the chronic and cancer analyses, average residues of parent plus metabolites were used.

Processing Factors

For most processed commodities, the residues used in the assessment accounted for concentration or reduction; however, HED used conservative default processing factors for dried potatoes (granules/flakes and flour), dried tomatoes, dried bell peppers, and dried nonball peppers.

Residues in Fish

The USDA Pesticide Data Program (PDP) monitored pesticide residues in catfish in 2008, 2009, and 2010 and salmon in 2013 and 2014. In general, pesticide residues would not be expected to be found in fish unless the pesticide bioaccumulates or has an aquatic use. To determine whether or not residues are present in fish, HED now routinely checks PDP monitoring data regardless of the pesticide's uses and physicochemical properties. PDP did not analyze fish samples for pymetrozine. As a result, HED did not include residues in fish in the dietary exposure assessments.

III. Percent Crop Treated Information

Acute Assessment

The acute assessment is based on the assumption that 100% of all commodities with tolerances will be treated with pymetrozine.

Chronic and Cancer Assessments

In the chronic and cancer dietary exposure assessments, HED used the average percent crop treated estimates provided by the Biological and Economic Analysis Division (BEAD) in its screening level usage analysis (SLUA) of April 27, 2016.

The following average percent crop treated estimates (SLUA, J. Alsadek, 4/27/2016) were used in the chronic dietary risk assessment for the following crops that are currently registered for pymetrozine: asparagus: 5%; broccoli: 2.5%; Brussels sprouts: 15%; cabbage: 5%; cantaloupe: 5%; cauliflower: 5%; celery: 20%; cucumber: 2.5%; lettuce, head: 5%; lettuce, leaf: 5%; pecan: 2.5%; pepper: 5%; potato: 5%; pumpkin: 2.5%; spinach: 2.5%; squash: 2.5%; tomato: 5%; watermelon: 2.5%.

The following average percent crop treated estimates (SLUA, J. Alsadek, 4/27/2016) were used in the cancer dietary risk assessments for the following crops that are currently registered for pymetrozine: asparagus: 5%; broccoli: 2.5%; Brussels sprouts: 15%; cabbage: 5%; cantaloupe: 5%; cauliflower: 5%; celery: 20%; cucumber: 2.5%; lettuce, head: 5%; lettuce, leaf: 5%; pecan: 2.5%; pepper: 5%; potato: 5%; pumpkin: 2.5%; spinach: 2.5%; squash: 2.5%; tomato: 5%; watermelon: 2.5%.

IV. Drinking Water Data

EFED prepared a drinking water assessment (DWA) for pymetrozine (J. Joyce and R. Bohaty, D439606, 8/24/2017). The following information relevant to the pymetrozine dietary exposure assessments is excerpted from that memorandum: “The DWA was completed using current models and guidance. Parent pymetrozine and six transformation products (CGA 359009, CGA 363431, CGA 363430, CGA 215525, Hydroxy CGA 215525, and CGA 294849) are the residues of concern considered per the Residues of Concern Knowledgebase Subcommittee (ROCKS) memorandum. All residues are assumed to have similar toxicity to parent, therefore, a total toxic residue (TTR) approach was utilized. Parent-only pymetrozine results are provided for comparison.

All modeled use scenarios were developed based on pymetrozine registered labels and in consultation with the Biological and Economic Analysis Division (BEAD) of the Office of Pesticide Programs (OPP). Estimated drinking water concentrations (EDWCs) for surface water and groundwater for pymetrozine and total toxic pymetrozine residues are provided in Table 1. In addition to providing EDWCs for maximum label use rates, EDWCs for use on potatoes (a major use for pymetrozine) based on typical application rates are also included for characterization.

Based on maximum label use rates, TTR EDWCs from sourced surface water are not expected to exceed 47 µg/L as the daily average surface water concentration, 13 µg/L for the 1 in 10 year-annual average, and 10 µg/L for the 30-year annual average in the dietary risk assessment. EDWCs resulting from groundwater from vulnerable wells are not expected to exceed 404 µg/L as the peak groundwater concentration, and 367 µg/L as the post-breakthrough average. The

EDWCs decrease by approximately 5X when typical use rates are utilized, and are not expected to exceed 89 µg/L as the peak groundwater concentration, and 79 µg/L as the post-breakthrough average.

EFED recommends that the Health Effects Division (HED) use 404 µg/L as the peak groundwater concentration, and 367 µg/L as the post-breakthrough average in the dietary risk assessment.”

Table 1. Estimated Drinking Water Concentrations of Pymetrozine and Total Toxic Residues						
Drinking Water Source	Use Site; Modeled Source	Residue	Application Rate	EDWCs from Pesticide Root Zone Model – Variable Volume Water Model (PRZM-VVWM)		
				1-in-10 Year Concentration (µg/L)		30 Year Annual Average Concentration (µg/L)
				Daily Average	Annual Average	
Surface Water	Outdoor – Christmas trees, Ornamentals, & Fruits (Nonbearing fruit and nut trees in nurseries); Index Reservoir	Pymetrozine	Maximum Use Rate ^a	23	5	3
		TTR		47	13	10
				EDWCs from Pesticide Root Zone Model – Groundwater (PRZM-GW) Concentration (µg/L)		
				Peak	Post-Breakthrough Average	
Groundwater	Outdoor – Christmas trees, Ornamentals, & Fruits (Nonbearing fruit and nut trees in nurseries); Unconfined well	Pymetrozine	Maximum Use Rate ^a	0.09	NA	
		TTR		404	367	
		Potatoes; Unconfined well	TTR	Typical Use Rate ^b	89	79
a) Total maximum single use rate from Endeavor and Mainspring Flora product labels: 0.3125 lb a.i./A (0.35 kg/ha) and 5 applications b) Typical use rate for potatoes: 0.172 lbs a.i./acre (0.193 kg/ha) with 2 applications based on the 90 th percentile NA – Not Applicable due to no breakthrough						

In accordance with EFED’s recommendation, HED used 404 ppb in the acute assessments and 367 ppb in the chronic assessments.

Because the EDWCs resulted in risk estimates of concern, HED requested that EFED provide refined EDWCs. EFED responded by providing EDWCs for scenarios other than the maximum labeled use rate. EFED generated EDWCs for the typical use rate on potatoes (a major use for pymetrozine), the lowest labeled maximum use rate, and the typical use rate on general vegetables. EFED generated the EDWCs using the Pesticide Root Zone Model-Groundwater

(PRZM-GW). These EDWCs are provided in the table below. HED performed cancer dietary exposure assessments based on these EDWCs for food and water and for water only.

Table 2. Chronic and Cancer EDWCs: Groundwater	
EDWC (ppb)	Application Scenario
367	Maximum Use Rate: Post-Breakthrough Average
79	Typical Use Rate on Potatoes
40	Lowest Maximum Use Rate
20	Typical Use Rate on General Vegetables

V. DEEM-FCID Program and Consumption Information

Acute, chronic, and cancer dietary exposure assessments were conducted for pymetrozine using the DEEM-FCID, Version 3.16, which incorporates 2003-2008 consumption data from USDA's NHANES/WWEIA. The data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g., apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups. However, for acute exposure assessment, consumption data are retained as individual consumption events. Based on analysis of the 2003-2008 WWEIA consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50-99 years old.

For a chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food-commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For an acute dietary exposure assessment, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant

commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for analyses performed at all levels of refinement. However, for deterministic assessments, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

VI. Toxicological Information

Adequate data have been submitted to characterize the toxicity of pymetrozine for the purposes of dietary risk assessment. HED selected acute, chronic, and cancer dietary endpoints for the chemical. The acute and chronic dietary endpoints are the same and were derived from the results of the rat developmental neurotoxicity study. The endpoint is based on morphometric changes in the brains of female rat pups on post-natal day 12 and male rat pups on post-natal day 63. The FQPA Safety Factor was retained at 10X for all population subgroups.

HED classified pymetrozine as a “likely human carcinogen,” and calculated a cancer potency factor of $0.0119 \text{ (mg/kg/day)}^{-1}$. The slope factor was based on male mouse liver combined benign hepatomas and/or hepatocarcinomas.

The doses and endpoints for dietary exposure assessment are summarized in the toxicological endpoint summary tables below.

Table 3. Summary of Toxicological Doses and Endpoints for Pymetrozine for Use in Dietary and Non-Occupational Human Health Risk Assessments				
Exposure/Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All Populations)	Offspring LOAEL = 8.1 mg/kg/day	UF _A = 10X UF _H = 10X FQPA SF/UF _L = 10X	Acute RfD = 0.081 mg/kg/day aPAD = 0.008 mg/kg/day	<u>Developmental Neurotoxicity (Rat)</u> Offspring LOAEL = 8.1 mg/kg/day, based on morphometric changes in the brains of female pups on PND 12 and male pups on PND 63.
Chronic Dietary (All Populations)	Offspring LOAEL = 8.1 mg/kg/day	UF _A = 10X UF _H = 10X FQPA SF/UF _L = 10X	Chronic RfD = 0.081 mg/kg/day cPAD = 0.008 mg/kg/day	<u>Developmental Neurotoxicity (Rat)</u> Offspring LOAEL = 8.1 mg/kg/day, based on morphometric changes in the brains of female pups on PND 12 and male pups on PND 63.
Cancer (oral, dermal, inhalation)	Classification: “likely human carcinogen.” A cancer potency factor of $0.0119 \text{ (mg/kg/day)}^{-1}$ was calculated for pymetrozine based on male mouse liver combined benign hepatoma and/or hepatocarcinoma.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = extrapolation from LOAEL to NOAEL. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose (a = acute, c = chronic).

VII. Results/Discussion

As stated above, for acute and chronic assessments, HED is concerned when dietary risk estimates exceed 100% of the PAD. The DEEM-FCID analyses estimate the dietary exposure and risk of the general U.S. population and various population subgroups. The results reported in Tables 4 and 5 are for the general U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50-99 years.

Results of Acute Dietary Exposure and Risk Assessments

For food only, the acute dietary risk estimates are not of concern. The general U.S. population uses 27% of the aPAD at the 95th percentile of exposure. The most highly exposed population subgroup, Children 1-2 years old uses 45% of the aPAD. Acute dietary risks are of concern when residues in drinking water are included in the dietary exposure assessments. For the assessments that include drinking water only and food plus drinking water, the general U.S. population uses 270% and 290% of the aPAD, respectively. The most highly exposed population subgroup, All Infants, uses 850% of the aPAD for drinking water alone as well as food plus drinking water. The results of the chronic dietary exposure assessments are summarized in Table 4, below.

Results of Chronic Dietary (Food Only) Exposure and Risk Assessments

For food only, the chronic dietary risk estimates are not of concern. The general U.S. population and all population subgroups use <1% of the cPAD. Chronic dietary risk estimates are of concern for some population subgroups, but not for others, when residues in drinking water are included. The general U.S. population uses 95% of the cPAD when the assessments include drinking water only and food plus drinking water. The most highly exposed population subgroup, All Infants, uses 240% of the cPAD for drinking water alone as well as for food plus drinking water. The results of the chronic dietary exposure assessments are summarized in Table 5, below.

Results of Cancer Dietary Risk Assessments

HED determines cancer risk for the adult subpopulation with the highest exposure estimate. For pymetrozine, that subgroup is Adults 20-49 for all scenarios analyzed. For the assessments that included food and drinking water, cancer risk estimates ranged from 5.7×10^{-6} (20 ppb EDWC) to 9.2×10^{-5} (367 ppb EDWC). For the assessments that included drinking water only, cancer risk estimates ranged from 5.0×10^{-6} (20 ppb EDWC) to 9.1×10^{-5} (367 ppb EDWC). For food only, the cancer risk estimate is 7.1×10^{-7} . The results of the cancer dietary exposure assessments are summarized in Tables 6 and 7, below.

**Table 4. Summary of Acute Dietary Exposure and Risk at the 95th Percentile of Exposure
EDWC: 404 ppb (Groundwater Maximum Use Rate)**

Population Subgroup	Food and Drinking Water		Drinking Water Only		Food Only	
	Dietary Exposure (mg/kg/day)	% aPAD 95 th %ile	Dietary Exposure (mg/kg/day)	% aPAD 95 th %ile	Dietary Exposure (mg/kg/day)	% aPAD 95 th %ile
General U.S. Population	0.023161	290	0.022029	270	0.002221	27
All Infants (<1 year old)*	0.069019	850	0.068998	850	0.001520	19
Children 1-2 years old*	0.035390	440	0.033969	420	0.003618	45
Children 3-5 years old	0.029122	360	0.027564	340	0.003520	43
Children 6-12 years old	0.022067	270	0.021061	260	0.002161	27
Youth 13-19 years old	0.018952	230	0.018346	230	0.001772	22
Adults 20-49 years old	0.022704	280	0.021678	270	0.002256	28
Adults 50-99 years old	0.020428	250	0.019310	240	0.002076	26
Females 13-49 years old	0.023132	290	0.021987	270	0.002207	27

*The subpopulation with the highest exposure estimates.

**Table 5. Summary of Chronic Dietary Exposure and Risk for Pymetrozine
EDWC: 367 ppb (Groundwater Post Breakthrough Average)**

Population Subgroup	Food and Drinking Water		Drinking Water Only		Food Only	
	Dietary Exposure (mg/kg/day)	% cPAD*	Dietary Exposure (mg/kg/day)	% cPAD*	Dietary Exposure (mg/kg/day)	% cPAD*
General U.S. Population	0.007727	95	0.007685	95	0.000042	<1
All Infants (<1 year old)	0.019829	240	0.019815	240	0.000014	<1
Children 1-2 years old*	0.011112	140	0.011085	140	0.000026	<1
Children 3-5 years old	0.009364	120	0.009340	120	0.000025	<1
Children 6-12 years old	0.006754	83	0.006736	83	0.000018	<1
Youth 13-19 years old	0.005622	69	0.005604	69	0.000018	<1
Adults 20-49 years old	0.007726	95	0.007667	95	0.000060	<1
Adults 50-99 years old	0.007618	94	0.007580	94	0.000039	<1
Females 13-49 years old	0.007670	95	0.007639	94	0.000032	<1

*The subpopulation with the highest exposure estimates.

Table 6. Cancer Dietary Risk Estimates for Food and Drinking Water

Adult Subgroup with Highest Risk Estimate	EDWC (ppb)	Cancer Risk Estimate
Adults 20-49	367	9.2×10^{-5}
Adults 20-49	79	2.0×10^{-5}
Adults 20-49	40	1.1×10^{-5}
Adults 20-49	20	5.7×10^{-6}

Table 7. Cancer Dietary Risk Estimates for Drinking Water Only		
Adult Subgroup with Highest Risk Estimate	EDWC (ppb)	Cancer Risk Estimate
Adults 20-49	367	9.1×10^{-5}
Adults 20-49	79	2.0×10^{-5}
Adults 20-49	40	9.9×10^{-6}
Adults 20-49	20	5.0×10^{-6}

Contribution of Residues in Drinking Water

In the acute, chronic, and cancer dietary exposure assessments, residues in drinking water were the primary contributor to dietary exposure and risk. In the acute assessment, the most highly exposed population subgroup, All Infants, used 850% of the aPAD when residues in drinking water were included, regardless of whether or not residues in food were included. This same population subgroup used 19% of the aPAD when residues in food only were included. In the chronic assessment, the most highly exposed population subgroup, All Infants, used 240% of the cPAD when residues in drinking water were included, regardless of whether or not residues in food were included. This same population subgroup used <1% of the cPAD when residues in food only were included. In the cancer assessment, the risk estimate is 7.5×10^{-7} when residues in food only are included. When residues in drinking water are included, as the EDWCs increase from 20 ppb to 367 ppb, the risk estimates increase from 5.0×10^{-6} to 9.1×10^{-5} .

VIII. Characterization of Inputs/Outputs

The acute, chronic, and cancer dietary exposure assessments are partially refined assessments based on anticipated residues calculated from results of field trial studies. For the acute analysis, maximum residues of parent plus metabolites were used, and for the chronic and cancer analyses, average residues of parent plus metabolites were used. For pymetrozine, residues in food are a minor contributor to dietary risk, however. Residues in drinking water are the primary contributors to acute, chronic, and cancer dietary risk. When refined EDWCs based on alternate use rates or more restricted uses are incorporated into the cancer assessment, the cancer risk estimates still exceed 1×10^{-6} , however.

IX. Conclusions

For pymetrozine, acute, chronic, and cancer dietary risk estimates generally exceed the level of concern, based on dietary exposure assessments that incorporate refined residue estimates in food and EDWCs that include all residues of toxicological concern. Residues in food are a minor contributor to dietary risk, however. Residues in drinking water are the primary contributors to acute, chronic, and cancer dietary risk. When refined EDWCs based on alternate use rates or more restricted uses are incorporated into the cancer assessment, the cancer risk estimates still exceed 1×10^{-6} , however.

X. List of Attachments

1. Table of Dietary Exposure Inputs
2. Acute Dietary Data Input File
3. Results of Acute Dietary Exposure Assessment: Food and Drinking Water
4. Results of Acute Dietary Exposure Assessment: Drinking Water Only
5. Results of Acute Dietary Exposure Assessment: Food Only
6. Chronic Dietary Data Input File
7. Results of Chronic Dietary Exposure Assessment: Food and Drinking Water
8. Results of Chronic Dietary Exposure Assessment: Drinking Water Only
9. Results of Chronic Dietary Exposure Assessment: Food Only
10. Results of Cancer Dietary Exposure Assessments
11. Pymetrozine SLUA

Attachment 1. Table of Dietary Exposure Inputs

Residue Inputs, Processing Factors and Percent Crop Treated Estimates Used in the Pymetrozine Assessments

Commodity	Residue Estimates, ppm			Factors	% Crop Treated Estimates	
	Acute	Chronic	Cancer	Processing	Maximum (Acute)	Average (Chronic)
Amaranth, leafy	0.726	0.21921	0.21921	1.00	100	100
Arrowroot, flour	0.046	0.0046	0.0046	1.00	100	100
Arrowroot, flour- babyfood	0.046	0.0046	0.0046	1.00	100	100
Artichoke, Jerusalem	0.046	0.0046	0.0046	1.00	100	100
Arugula	0.726	0.18537	0.18537	1.00	100	100
Asparagus	0.04	0.04	0.04	1.00	100	5
Balsam pear	0.13	0.066	0.06181	1.00	100	100
Broccoli	0.6278	0.05314	0.05314	1.00	100	2.5
Broccoli- babyfood	0.6278	0.05314	0.05314	1.00	100	2.5
Broccoli raab	0.358	0.26369	0.26369	1.00	100	100
Broccoli, Chinese	0.6278	0.05314	0.05314	1.00	100	100
Brussels sprouts	0.6278	0.07906	0.07906	1.00	100	15
Cabbage	0.6278	0.07906	0.07906	1.00	100	5
Cabbage, Chinese, bok choy	0.358	0.26369	0.26369	1.00	100	100
Cabbage, Chinese, mustard	0.6278	0.05314	0.05314	1.00	100	100
Cabbage, Chinese, napa	0.6278	0.05314	0.05314	1.00	100	100
Cantaloupe	0.13	0.066	0.066	1.00	100	100
Cardoon	0.726	0.06362	0.06362	1.00	100	100
Casaba	0.13	0.066	0.066	1.00	100	100
Cassava	0.046	0.0046	0.0046	1.00	100	100
Cassava- babyfood	0.046	0.0046	0.0046	1.00	100	100
Cauliflower	0.6278	0.05314	0.05314	1.00	100	5
Celery	0.726	0.06362	0.06362	1.00	100	20
Celery- babyfood	0.726	0.06362	0.06362	1.00	100	20
Celery, juice	0.726	0.06362	0.06362	1.00	100	20
Celtuce	0.726	0.06362	0.06362	1.00	100	100
Chayote, fruit	0.13	0.066	0.066	1.00	100	100
Chinese waxgourd	0.13	0.066	0.066	1.00	100	100
Chrysanthemum, garland	0.726	0.21921	0.21921	1.00	100	100
Collards	0.358	0.26369	0.26369	1.00	100	100
Cottonseed, oil	0.3936	0.084	0.084	1.00	100	100
Cottonseed, oil - babyfood	0.3936	0.084	0.084	1.00	100	100

Commodity	Residue Estimates, ppm			Factors	% Crop Treated Estimates	
	Acute	Chronic	Cancer	Processing	Maximum (Acute)	Average (Chronic)
Cress, garden	0.726	0.21921	0.21921	1.00	100	100
Cress, upland	0.726	0.21921	0.21921	1.00	100	100
Cucumber	0.13	0.06181	0.06181	1.00	100	2.5
Dandelion, leaves	0.726	0.21921	0.21921	1.00	100	100
Dasheen, corm	0.046	0.0046	0.0046	1.00	100	100
Eggplant	0.23	0.052333	0.052333	1.00	100	100
Endive	0.726	0.21921	0.21921	1.00	100	100
Fennel, Florence	0.726	0.06362	0.06362	1.00	100	100
Ginger	0.046	0.0046	0.0046	1.00	100	100
Ginger - babyfood	0.046	0.0046	0.0046	1.00	100	100
Ginger, dried	0.046	0.0046	0.0046	1.00	100	100
Honeydew melon	0.13	0.066	0.066	1.00	100	100
Hop	6.18	2.784	2.784	1.00	100	100
Kale	0.358	0.26369	0.26369	1.00	100	100
Kohlrabi	0.6278	0.07906	0.07906	1.00	100	100
Lettuce, head	0.726	0.062	0.062	1.00	100	5
Lettuce, leaf	0.726	0.18537	0.18537	1.00	100	5
Mustard greens	0.358	0.26369	0.26369	1.00	100	100
Okra	0.23	0.052333	0.052333	1.00	100	100
Parsley, leaves	0.726	0.21921	0.21921	1.00	100	100
Pecan	0.056	0.046	0.046	1.00	100	100
Pepper, bell	0.23	0.052333	0.052333	1.00	100	5
Pepper, bell- babyfood	0.23	0.052333	0.052333	1.00	100	5
Pepper, bell, dried	0.23	0.052333	0.052333	13.5	100	5
Pepper, bell, dried- babyfood	0.23	0.052333	0.052333	13.5	100	5
Pepper, non-bell	0.23	0.052333	0.052333	1.00	100	5
Pepper, non-bell, - babyfood	0.23	0.052333	0.052333	1.00	100	5
Pepper, non-bell, dried	0.23	0.052333	0.052333	12.8	100	5
Potato, chips	0.046	0.0046	0.0046	1.00	100	5
Potato, dry (granules/ flakes)- babyfood	0.046	0.0046	0.0046	6.50	100	5
Potato, dry (granules/ flakes)	0.046	0.0046	0.0046	6.50	100	5
Potato, flour	0.046	0.0046	0.0046	6.50	100	5
Potato, flour - babyfood	0.046	0.0046	0.0046	6.50	100	5
Potato, tuber, w/o peel	0.046	0.0046	0.0046	1.00	100	5
Potato, tuber, w/o peel- babyfood	0.046	0.0046	0.0046	1.00	100	5
Potato, tuber, w/peel	0.046	0.0046	0.0046	1.00	100	5

Commodity	Residue Estimates, ppm			Factors	% Crop Treated Estimates	
	Acute	Chronic	Cancer	Processing	Maximum (Acute)	Average (Chronic)
Potato, tuber, w/peel- babyfood	0.046	0.0046	0.0046	1.00	100	5
Pumpkin	0.13	0.0601	0.0601	1.00	100	2.5
Pumpkin, seed	0.13	0.0601	0.0601	1.00	100	2.5
Radicchio	0.726	0.21921	0.21921	1.00	100	100
Rape greens	0.358	0.26369	0.26369	1.00	100	100
Rhubarb	0.726	0.06362	0.06362	1.00	100	100
Spinach	0.726	0.21921	0.21921	1.00	100	2.5
Spinach- babyfood	0.726	0.21921	0.21921	1.00	100	2.5
Squash, summer	0.13	0.0601	0.0601	1.00	100	2.5
Squash, summer- babyfood	0.13	0.0601	0.0601	1.00	100	2.5
Squash, winter	0.13	0.0601	0.0601	1.00	100	2.5
Squash, winter- babyfood	0.13	0.0601	0.0601	1.00	100	2.5
Sweet potato	0.046	0.0046	0.0046	1.00	100	100
Sweet potato- babyfood	0.046	0.0046	0.0046	1.00	100	100
Swiss chard	0.726	0.06362	0.06362	1.00	100	100
Tanier, corm	0.046	0.0046	0.0046	1.00	100	100
Tomatillo	0.23	0.052333	0.052333	1.00	100	100
Tomato	0.23	0.056125	0.056125	1.00	100	5
Tomato- babyfood	0.23	0.056125	0.056125	1.00	100	5
Tomato, dried	0.23	0.056125	0.056125	14.30	100	5
Tomato, dried - babyfood	0.23	0.056125	0.056125	14.30	100	5
Tomato, juice	0.102	0.04984	0.04984	1.00	100	5
Tomato, paste	0.225	0.17284	0.17284	1.00	100	5
Tomato, paste- babyfood	0.225	0.17284	0.17284	1.00	100	5
Tomato, puree	0.102	0.04984	0.04984	1.00	100	5
Tomato, puree- babyfood	0.102	0.04984	0.04984	1.00	100	5
Turmeric	0.046	0.0046	0.0046	1.00	100	100
Turnip, tops	0.358	0.26369	0.26369	1.00	100	100
Watermelon	0.13	0.066	0.066	1.00	100	2.5
Watermelon, juice	0.13	0.066	0.066	1.00	100	2.5
Yam bean	0.046	0.0046	0.0046	1.00	100	100
Yam, true	0.046	0.0046	0.0046	1.00	100	100
Drinking Water	404 ppb	367 ppb	367, 79, 40, 20 ppb	-	-	-

Attachment 2. Acute Dietary Data Input File

Filename: C:\Users\ddotson\Documents\DEEM Version 3.16\Pymetrozine 2017
 DRA\PymetrozineAcuteFoodandWater.R08
 Chemical: Pymetrozine
 RfD(Chronic): .0081 mg/kg bw/day NOEL(Chronic): 8.1 mg/kg bw/day
 RfD(Acute): .0081 mg/kg bw/day NOEL(Acute): 8.1 mg/kg bw/day Q*= .0119
 Date created/last modified: 11-28-2017/10:33:08 Program ver. 3.16, 03-08-d

EPA Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Factors #1	#2	Comment
0103015000	1CD	Arrowroot, flour	0.046000	1.000	1.000	
0103015001	1CD	Arrowroot, flour-babyfood	0.046000	1.000	1.000	
0103017000	1CD	Artichoke, Jerusalem	0.046000	1.000	1.000	
0103082000	1CD	Cassava	0.046000	1.000	1.000	
0103082001	1CD	Cassava-babyfood	0.046000	1.000	1.000	
0103139000	1CD	Dasheen, corm	0.046000	1.000	1.000	
0103166000	1CD	Ginger	0.046000	1.000	1.000	
0103166001	1CD	Ginger-babyfood	0.046000	1.000	1.000	
0103167000	1CD	Ginger, dried	0.046000	1.000	1.000	
0103296000	1C	Potato, chips	0.046000	1.000	1.000	
0103297000	1C	Potato, dry (granules/ flakes)	0.046000	6.500	1.000	
0103297001	1C	Potato, dry (granules/ flakes)-b	0.046000	6.500	1.000	
0103298000	1C	Potato, flour	0.046000	6.500	1.000	
0103298001	1C	Potato, flour-babyfood	0.046000	6.500	1.000	
0103299000	1C	Potato, tuber, w/peel	0.046000	1.000	1.000	
0103299001	1C	Potato, tuber, w/peel-babyfood	0.046000	1.000	1.000	
0103300000	1C	Potato, tuber, w/o peel	0.046000	1.000	1.000	
0103300001	1C	Potato, tuber, w/o peel-babyfood	0.046000	1.000	1.000	
0103366000	1CD	Sweet potato	0.046000	1.000	1.000	
0103366001	1CD	Sweet potato-babyfood	0.046000	1.000	1.000	
0103371000	1CD	Tanier, corm	0.046000	1.000	1.000	
0103387000	1CD	Turmeric	0.046000	1.000	1.000	
0103406000	1CD	Yam, true	0.046000	1.000	1.000	
0103407000	1CD	Yam bean	0.046000	1.000	1.000	
0401005000	4A	Amaranth, leafy	0.726000	1.000	1.000	
0401018000	4A	Arugula	0.726000	1.000	1.000	
0401104000	4A	Chrysanthemum, garland	0.726000	1.000	1.000	
0401133000	4A	Cress, garden	0.726000	1.000	1.000	
0401134000	4A	Cress, upland	0.726000	1.000	1.000	
0401138000	4A	Dandelion, leaves	0.726000	1.000	1.000	
0401150000	4A	Endive	0.726000	1.000	1.000	
0401204000	4A	Lettuce, head	0.726000	1.000	1.000	
0401205000	4A	Lettuce, leaf	0.726000	1.000	1.000	
0401248000	4A	Parsley, leaves	0.726000	1.000	1.000	
0401313000	4A	Radicchio	0.726000	1.000	1.000	
0401355000	4A	Spinach	0.726000	1.000	1.000	
0401355001	4A	Spinach-babyfood	0.726000	1.000	1.000	
0402076000	4B	Cardoon	0.726000	1.000	1.000	
0402085000	4B	Celery	0.726000	1.000	1.000	
0402085001	4B	Celery-babyfood	0.726000	1.000	1.000	
0402086000	4B	Celery, juice	0.726000	1.000	1.000	
0402087000	4B	Celtuce	0.726000	1.000	1.000	
0402152000	4B	Fennel, Florence	0.726000	1.000	1.000	
0402322000	4B	Rhubarb	0.726000	1.000	1.000	
0402367000	4B	Swiss chard	0.726000	1.000	1.000	
0501061000	5A	Broccoli	0.627800	1.000	1.000	
0501061001	5A	Broccoli-babyfood	0.627800	1.000	1.000	

0501062000	5A	Broccoli, Chinese	0.627800	1.000	1.000
0501064000	5A	Brussels sprouts	0.627800	1.000	1.000
0501069000	5A	Cabbage	0.627800	1.000	1.000
0501071000	5A	Cabbage, Chinese, napa	0.627800	1.000	1.000
0501072000	5A	Cabbage, Chinese, mustard	0.627800	1.000	1.000
0501083000	5A	Cauliflower	0.627800	1.000	1.000
0501196000	5A	Kohlrabi	0.627800	1.000	1.000
0502063000	5B	Broccoli raab	0.358000	1.000	1.000
0502070000	5B	Cabbage, Chinese, bok choy	0.358000	1.000	1.000
0502117000	5B	Collards	0.358000	1.000	1.000
0502194000	5B	Kale	0.358000	1.000	1.000
0502229000	5B	Mustard greens	0.358000	1.000	1.000
0502318000	5B	Rape greens	0.358000	1.000	1.000
0502389000	5B	Turnip, greens	0.358000	1.000	1.000
0801374000	8A	Tomatillo	0.230000	1.000	1.000
0801375000	8A	Tomato	0.230000	1.000	1.000
0801375001	8A	Tomato-babyfood	0.230000	1.000	1.000
0801376000	8A	Tomato, paste	0.225000	1.000	1.000
0801376001	8A	Tomato, paste-babyfood	0.225000	1.000	1.000
0801377000	8A	Tomato, puree	0.102000	1.000	1.000
0801377001	8A	Tomato, puree-babyfood	0.102000	1.000	1.000
0801378000	8A	Tomato, dried	0.230000	14.300	1.000
0801378001	8A	Tomato, dried-babyfood	0.230000	14.300	1.000
0801379000	8A	Tomato, juice	0.102000	1.000	1.000
0801380000	8A	Tomato, Tree	0.230000	1.000	1.000
0802148000	8BC	Eggplant	0.230000	1.000	1.000
0802234000	8BC	Okra	0.230000	1.000	1.000
0802270000	8B	Pepper, bell	0.230000	1.000	1.000
0802270001	8B	Pepper, bell-babyfood	0.230000	1.000	1.000
0802271000	8B	Pepper, bell, dried	0.230000	13.500	1.000
0802271001	8B	Pepper, bell, dried-babyfood	0.230000	13.500	1.000
0802272000	8BC	Pepper, nonbell	0.230000	1.000	1.000
0802272001	8BC	Pepper, nonbell-babyfood	0.230000	1.000	1.000
0802273000	8BC	Pepper, nonbell, dried	0.230000	12.800	1.000
0901075000	9A	Cantaloupe	0.130000	1.000	1.000
0901187000	9A	Honeydew melon	0.130000	1.000	1.000
0901399000	9A	Watermelon	0.130000	1.000	1.000
0901400000	9A	Watermelon, juice	0.130000	1.000	1.000
0902021000	9B	Balsam pear	0.130000	1.000	1.000
0902088000	9B	Chayote, fruit	0.130000	1.000	1.000
0902102000	9B	Chinese waxgourd	0.130000	1.000	1.000
0902135000	9B	Cucumber	0.130000	1.000	1.000
0902308000	9B	Pumpkin	0.130000	1.000	1.000
0902309000	9B	Pumpkin, seed	0.130000	1.000	1.000
0902356000	9B	Squash, summer	0.130000	1.000	1.000
0902356001	9B	Squash, summer-babyfood	0.130000	1.000	1.000
0902357000	9B	Squash, winter	0.130000	1.000	1.000
0902357001	9B	Squash, winter-babyfood	0.130000	1.000	1.000
1400269000	14	Pecan	0.046000	1.000	1.000
2003128000	20C	Cottonseed, oil	0.393600	1.000	1.000
2003128001	20C	Cottonseed, oil-babyfood	0.393600	1.000	1.000
8601000000	86A	Water, direct, all sources	0.404000	1.000	1.000
8602000000	86B	Water, indirect, all sources	0.404000	1.000	1.000
9500019000	O	Asparagus	0.040000	1.000	1.000
9500188000	O	Hop	6.180000	1.000	1.000

Attachment 3. Results of Acute Dietary Exposure Assessment: Food and Water

US EPA
 DEEM-FCID ACUTE Analysis for PYMETROZINE
 Residue file: PymetrozineAcuteFoodandWater.R08
 Analysis Date: 11-28-2017/10:46:31
 NOEL (Acute) = 8.100000 mg/kg body-wt/day
 RAC/FF intake summed over 24 hours
 Run Comment: ""

Ver. 3.18, 03-08-d
 NHANES 2003-2008 2-Day
 Adjustment factor #2 NOT used.
 Residue file dated: 11-28-2017/10:33:08

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Summary calculations--per capita:

--- 95th Percentile---			--- 99th Percentile---			---99.9th Percentile---		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
Total US Population:								
0.023161	285.94	349	0.037406	461.80	216	0.069383	856.58	116
All Infants:								
0.069019	852.09	117	0.093443	1153.62	86	0.138044	1704.25	58
Children 1-2:								
0.035390	436.91	228	0.052141	643.72	155	0.125863	1553.87	64
Children 3-5:								
0.029122	359.54	278	0.043626	538.60	185	0.069310	855.68	116
Children 6-12:								
0.022067	272.43	367	0.034950	431.48	231	0.053395	659.20	151
Youth 13-19:								
0.018952	233.98	427	0.031068	383.55	260	0.046259	571.10	175
Adults 20-49:								
0.022704	280.29	356	0.033097	408.60	244	0.047286	583.78	171
Adults 50-99:								
0.020428	252.20	396	0.030506	376.61	265	0.046373	572.51	174
Female 13-49:								
0.023132	285.58	350	0.033330	411.49	243	0.045966	567.48	176

Attachment 4. Results of Acute Dietary Exposure Assessment: Drinking Water Only

US EPA
 DEEM-FCID ACUTE Analysis for PYMETROZINE
 Residue file: PymetrozineAcuteWaterOnly.R08
 Analysis Date: 12-07-2017/17:04:27
 NOEL (Acute) = 8.100000 mg/kg body-wt/day
 RAC/FF intake summed over 24 hours
 Run Comment: ""

Ver. 3.18, 03-08-d
 NHANES 2003-2008 2-Day
 Adjustment factor #2 NOT used.
 Residue file dated: 11-27-2017/09:59:46

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Summary calculations--per capita:

--- 95th Percentile----			--- 99th Percentile----			---99.9th Percentile----		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
Total US Population:								
0.022029	271.96	367	0.036326	448.47	222	0.069007	851.93	117
All Infants:								
0.068998	851.83	117	0.093458	1153.80	86	0.136973	1691.03	59
Children 1-2:								
0.033969	419.38	238	0.051151	631.49	158	0.125970	1555.19	64
Children 3-5:								
0.027564	340.29	293	0.042215	521.17	191	0.067760	836.54	119
Children 6-12:								
0.021061	260.01	384	0.034563	426.71	234	0.053273	657.69	152
Youth 13-19:								
0.018346	226.49	441	0.030216	373.04	268	0.045621	563.22	177
Adults 20-49:								
0.021678	267.63	373	0.032260	398.27	251	0.046932	579.41	172
Adults 50-99:								
0.019310	238.40	419	0.029280	361.48	276	0.046154	569.80	175
Female 13-49:								
0.021987	271.44	368	0.032331	399.15	250	0.045342	559.78	178

Attachment 5. Results of Acute Dietary Exposure Assessment: Food Only

US EPA
 DEEM-FCID ACUTE Analysis for PYMETROZINE
 Residue file: PymetrozineAcuteFoodOnly.R08
 Analysis Date: 12-07-2017/17:08:17
 NOEL (Acute) = 8.100000 mg/kg body-wt/day
 RAC/FF intake summed over 24 hours
 Run Comment: ""

Ver. 3.18, 03-08-d
 NHANES 2003-2008 2-Day
 Adjustment factor #2 NOT used.

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Summary calculations--per capita:

--- 95th Percentile----			--- 99th Percentile----			---99.9th Percentile----		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
Total US Population:								
0.002221	27.41	3647	0.003835	47.35	2112	0.006787	83.78	1193
All Infants:								
0.001520	18.77	5327	0.004270	52.72	1896	0.008965	110.68	903
Children 1-2:								
0.003618	44.67	2238	0.006805	84.02	1190	0.009786	120.81	827
Children 3-5:								
0.003520	43.46	2301	0.006352	78.42	1275	0.012034	148.57	673
Children 6-12:								
0.002161	26.68	3748	0.004490	55.43	1804	0.007040	86.92	1150
Youth 13-19:								
0.001772	21.88	4571	0.003043	37.57	2661	0.005506	67.98	1471
Adults 20-49:								
0.002256	27.85	3590	0.003652	45.08	2218	0.006435	79.44	1258
Adults 50-99:								
0.002076	25.63	3901	0.003236	39.95	2502	0.005208	64.29	1555
Female 13-49:								
0.002207	27.25	3669	0.003713	45.84	2181	0.006482	80.03	1249

Attachment 6. Chronic Dietary Data Input File

Filename: C:\Users\ddotson\Documents\DEEM Version 3.16\Pymetrozine 2017
 DRA\PymetrozineChronicFoodandWater.R08
 Chemical: Pymetrozine
 RfD(Chronic): .0081 mg/kg bw/day NOEL(Chronic): 8.1 mg/kg bw/day
 RfD(Acute): .0081 mg/kg bw/day NOEL(Acute): 8.1 mg/kg bw/day Q*= .0119
 Date created/last modified: 12-07-2017/14:32:29 Program ver. 3.16, 03-08-d

EPA Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Factors #1	#2	Comment
0103015000	1CD	Arrowroot, flour	0.004600	1.000	1.000	
0103015001	1CD	Arrowroot, flour-babyfood	0.004600	1.000	1.000	
0103017000	1CD	Artichoke, Jerusalem	0.004600	1.000	1.000	
0103082000	1CD	Cassava	0.004600	1.000	1.000	
0103082001	1CD	Cassava-babyfood	0.004600	1.000	1.000	
0103139000	1CD	Dasheen, corm	0.004600	1.000	1.000	
0103166000	1CD	Ginger	0.004600	1.000	1.000	
0103166001	1CD	Ginger-babyfood	0.004600	1.000	1.000	
0103167000	1CD	Ginger, dried	0.004600	1.000	1.000	
0103296000	1C	Potato, chips	0.004600	1.000	0.050	
0103297000	1C	Potato, dry (granules/ flakes)	0.004600	6.500	0.050	
0103297001	1C	Potato, dry (granules/ flakes)-b	0.004600	6.500	0.050	
0103298000	1C	Potato, flour	0.004600	6.500	0.050	
0103298001	1C	Potato, flour-babyfood	0.004600	6.500	0.050	
0103299000	1C	Potato, tuber, w/peel	0.004600	1.000	0.050	
0103299001	1C	Potato, tuber, w/peel-babyfood	0.004600	1.000	0.050	
0103300000	1C	Potato, tuber, w/o peel	0.004600	1.000	0.050	
0103300001	1C	Potato, tuber, w/o peel-babyfood	0.004600	1.000	0.050	
0103366000	1CD	Sweet potato	0.004600	1.000	1.000	
0103366001	1CD	Sweet potato-babyfood	0.004600	1.000	1.000	
0103371000	1CD	Tanier, corm	0.004600	1.000	1.000	
0103387000	1CD	Turmeric	0.004600	1.000	1.000	
0103406000	1CD	Yam, true	0.004600	1.000	1.000	
0103407000	1CD	Yam bean	0.004600	1.000	1.000	
0401005000	4A	Amaranth, leafy	0.219210	1.000	1.000	
0401018000	4A	Arugula	0.185370	1.000	1.000	
0401104000	4A	Chrysanthemum, garland	0.219210	1.000	1.000	
0401133000	4A	Cress, garden	0.219210	1.000	1.000	
0401134000	4A	Cress, upland	0.219210	1.000	1.000	
0401138000	4A	Dandelion, leaves	0.219210	1.000	1.000	
0401150000	4A	Endive	0.219210	1.000	1.000	
0401204000	4A	Lettuce, head	0.062000	1.000	0.050	
0401205000	4A	Lettuce, leaf	0.185370	1.000	0.050	
0401248000	4A	Parsley, leaves	0.219210	1.000	1.000	
0401313000	4A	Radicchio	0.219210	1.000	1.000	
0401355000	4A	Spinach	0.219210	1.000	0.025	
0401355001	4A	Spinach-babyfood	0.219210	1.000	0.025	
0402076000	4B	Cardoon	0.063620	1.000	1.000	
0402085000	4B	Celery	0.063620	1.000	0.200	
0402085001	4B	Celery-babyfood	0.063620	1.000	0.200	
0402086000	4B	Celery, juice	0.063620	1.400	0.200	
0402087000	4B	Celtuce	0.063620	1.000	1.000	
0402152000	4B	Fennel, Florence	0.063620	1.000	1.000	
0402322000	4B	Rhubarb	0.063620	1.000	1.000	
0402367000	4B	Swiss chard	0.063620	1.000	1.000	
0501061000	5A	Broccoli	0.053140	1.000	0.025	
0501061001	5A	Broccoli-babyfood	0.053140	1.000	0.025	

0501062000	5A	Broccoli, Chinese	0.053140	1.000	1.000
0501064000	5A	Brussels sprouts	0.079060	1.000	0.150
0501069000	5A	Cabbage	0.079060	1.000	0.050
0501071000	5A	Cabbage, Chinese, napa	0.053140	1.000	1.000
0501072000	5A	Cabbage, Chinese, mustard	0.053140	1.000	1.000
0501083000	5A	Cauliflower	0.053140	1.000	0.050
0501196000	5A	Kohlrabi	0.079060	1.000	1.000
0502063000	5B	Broccoli raab	0.263690	1.000	1.000
0502070000	5B	Cabbage, Chinese, bok choy	0.263690	1.000	1.000
0502117000	5B	Collards	0.263690	1.000	1.000
0502194000	5B	Kale	0.263690	1.000	1.000
0502229000	5B	Mustard greens	0.263690	1.000	1.000
0502318000	5B	Rape greens	0.263690	1.000	1.000
0502389000	5B	Turnip, greens	0.263690	1.000	1.000
0801374000	8A	Tomatillo	0.052333	1.000	1.000
0801375000	8A	Tomato	0.056125	1.000	0.050
0801375001	8A	Tomato-babyfood	0.056125	1.000	0.050
0801376000	8A	Tomato, paste	0.172840	1.000	0.050
0801376001	8A	Tomato, paste-babyfood	0.172840	1.000	0.050
0801377000	8A	Tomato, puree	0.049840	1.000	0.050
0801377001	8A	Tomato, puree-babyfood	0.049840	1.000	0.050
0801378000	8A	Tomato, dried	0.056125	14.300	0.050
0801378001	8A	Tomato, dried-babyfood	0.056125	14.300	0.050
0801379000	8A	Tomato, juice	0.049840	1.000	0.050
0801380000	8A	Tomato, Tree	0.056125	1.000	1.000
0802148000	8BC	Eggplant	0.052333	1.000	1.000
0802234000	8BC	Okra	0.052333	1.000	1.000
0802270000	8B	Pepper, bell	0.052333	1.000	0.050
0802270001	8B	Pepper, bell-babyfood	0.052333	1.000	0.050
0802271000	8B	Pepper, bell, dried	0.052333	13.500	0.050
0802271001	8B	Pepper, bell, dried-babyfood	0.052333	13.500	0.050
0802272000	8BC	Pepper, nonbell	0.052333	1.000	0.050
0802272001	8BC	Pepper, nonbell-babyfood	0.052333	1.000	0.050
0802273000	8BC	Pepper, nonbell, dried	0.052333	12.800	0.050
0901075000	9A	Cantaloupe	0.066000	1.000	0.050
0901187000	9A	Honeydew melon	0.066000	1.000	1.000
0901399000	9A	Watermelon	0.066000	1.000	0.025
0901400000	9A	Watermelon, juice	0.066000	1.000	0.025
0902021000	9B	Balsam pear	0.066000	1.000	1.000
0902088000	9B	Chayote, fruit	0.066000	1.000	1.000
0902102000	9B	Chinese waxgourd	0.066000	1.000	1.000
0902135000	9B	Cucumber	0.061810	1.000	0.025
0902308000	9B	Pumpkin	0.060100	1.000	0.025
0902309000	9B	Pumpkin, seed	0.060100	1.000	0.025
0902356000	9B	Squash, summer	0.060100	1.000	0.025
0902356001	9B	Squash, summer-babyfood	0.060100	1.000	0.025
0902357000	9B	Squash, winter	0.060100	1.000	0.025
0902357001	9B	Squash, winter-babyfood	0.060100	1.000	0.025
1400269000	14	Pecan	0.046000	1.000	0.025
2003128000	20C	Cottonseed, oil	0.084000	1.000	1.000
2003128001	20C	Cottonseed, oil-babyfood	0.084000	1.000	1.000
8601000000	86A	Water, direct, all sources	0.367000	1.000	1.000
8602000000	86B	Water, indirect, all sources	0.367000	1.000	1.000
9500019000	O	Asparagus	0.040000	1.000	0.050
9500188000	O	Hop	2.784000	1.000	1.000

Attachment 7: Results of Chronic Dietary Exposure Assessment: Food and Water

US EPA
 DEEM-FCID Chronic analysis for PYMETROZINE
 Residue file name: C:\Users\ddotson\Documents\DEEM Version 3.16\Pymetrozine 2017
 DRA\PymetrozineChronicFoodandWater.R08

Ver. 3.16, 03-08-d

NHANES 2003-2008 2-day

Adjustment factor #2 used.

Analysis Date 12-07-2017/17:34:08

Residue file dated: 12-07-2017/14:32:29

Reference dose (RfD, Chronic) = .0081 mg/kg bw/day

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Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd

Total US Population	0.007727	95.4%
Hispanic	0.007372	91.0%
Non-Hisp-White	0.007946	98.1%
Non-Hisp-Black	0.006391	78.9%
Non-Hisp-Other	0.008899	109.9%
Nursing Infants	0.006964	86.0%
Non-Nursing Infants	0.025575	315.7%
Female 13+ PREG	0.007254	89.6%
Children 1-6	0.009868	121.8%
Children 7-12	0.006423	79.3%
Male 13-19	0.005304	65.5%
Female 13-19/NP	0.005934	73.3%
Male 20+	0.007231	89.3%
Female 20+/NP	0.008104	100.0%
Seniors 55+	0.007462	92.1%
All Infants	0.019829	244.8%
Female 13-50	0.007679	94.8%
Children 1-2	0.011112	137.2%
Children 3-5	0.009364	115.6%
Children 6-12	0.006754	83.4%
Youth 13-19	0.005622	69.4%
Adults 20-49	0.007726	95.4%
Adults 50-99	0.007618	94.1%
Female 13-49	0.007670	94.7%

Attachment 8: Results of Chronic Dietary Exposure Assessment: Drinking Water Only

US EPA Ver. 3.16, 03-08-d
 DEEM-FCID Chronic analysis for PYMETROZINE NHANES 2003-2008 2-day
 Residue file name: C:\Users\ddotson\Documents\DEEM Version 3.16\Pymetrozine 2017
 DRA\PymetrozineChronicWaterOnly.R08

Adjustment factor #2 used.

Analysis Date 12-07-2017/17:35:59

Residue file dated: 12-07-2017/14:33:11

Reference dose (RfD, Chronic) = .0081 mg/kg bw/day

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Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd

Total US Population	0.007685	94.9%
Hispanic	0.007337	90.6%
Non-Hisp-White	0.007904	97.6%
Non-Hisp-Black	0.006341	78.3%
Non-Hisp-Other	0.008857	109.3%
Nursing Infants	0.006952	85.8%
Non-Nursing Infants	0.025559	315.5%
Female 13+ PREG	0.007236	89.3%
Children 1-6	0.009842	121.5%
Children 7-12	0.006407	79.1%
Male 13-19	0.005283	65.2%
Female 13-19/NP	0.005919	73.1%
Male 20+	0.007159	88.4%
Female 20+/NP	0.008071	99.6%
Seniors 55+	0.007430	91.7%
All Infants	0.019815	244.6%
Female 13-50	0.007648	94.4%
Children 1-2	0.011085	136.9%
Children 3-5	0.009340	115.3%
Children 6-12	0.006736	83.2%
Youth 13-19	0.005604	69.2%
Adults 20-49	0.007667	94.7%
Adults 50-99	0.007580	93.6%
Female 13-49	0.007639	94.3%

Attachment 9: Results of Chronic Dietary Exposure Assessment: Food Only

US EPA Ver. 3.16, 03-08-d
 DEEM-FCID Chronic analysis for PYMETROZINE NHANES 2003-2008 2-day
 Residue file name: C:\Users\ddotson\Documents\DEEM Version 3.16\Pymetrozine 2017
 DRA\PymetrozineChronicFoodOnly.R08
 Adjustment factor #2 used.
 Analysis Date 12-09-2017/09:58:46 Residue file dated: 12-09-2017/09:55:39
 Reference dose (RfD, Chronic) = .0081 mg/kg bw/day

Total exposure by population subgroup		
Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
Total US Population	0.000042	0.5%
Hispanic	0.000035	0.4%
Non-Hisp-White	0.000043	0.5%
Non-Hisp-Black	0.000050	0.6%
Non-Hisp-Other	0.000042	0.5%
Nursing Infants	0.000012	0.1%
Non-Nursing Infants	0.000015	0.2%
Female 13+ PREG	0.000018	0.2%
Children 1-6	0.000025	0.3%
Children 7-12	0.000017	0.2%
Male 13-19	0.000022	0.3%
Female 13-19/NP	0.000014	0.2%
Male 20+	0.000072	0.9%
Female 20+/NP	0.000033	0.4%
Seniors 55+	0.000033	0.4%
All Infants	0.000014	0.2%
Female 13-50	0.000031	0.4%
Children 1-2	0.000026	0.3%
Children 3-5	0.000025	0.3%
Children 6-12	0.000018	0.2%
Youth 13-19	0.000018	0.2%
Adults 20-49	0.000060	0.7%
Adults 50-99	0.000039	0.5%
Female 13-49	0.000032	0.4%

Attachment 10: Results of Cancer Dietary Exposure Assessments for Adult Population Subgroups

Results of Assessments Based on an EDWC of 367 ppb

Food and Drinking Water

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q* = .0119)
Adults 20-49	0.007726	9.19E-05
Adults 50-99	0.007618	9.07E-05
Female 13-49	0.007670	9.13E-05

Drinking Water Only

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q* = .0119)
Adults 20-49	0.007667	9.12E-05
Adults 50-99	0.007580	9.02E-05
Female 13-49	0.007639	9.09E-05

Results of Assessments Based on an EDWC of 79 ppb

Food and Drinking Water

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q* = .0119)
Adults 20-49	0.001710	2.03E-05
Adults 50-99	0.001670	1.99E-05
Female 13-49	0.001676	1.99E-05

Drinking Water Only

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q* = .0119)
Adults 20-49	0.001650	1.96E-05
Adults 50-99	0.001632	1.94E-05
Female 13-49	0.001644	1.96E-05

Results of Assessments Based on an EDWC of 40 ppb

Food and Drinking Water

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q* = .0119)
Adults 20-49	0.000895	1.07E-05
Adults 50-99	0.000865	1.03E-05
Female 13-49	0.000864	1.03E-05

Drinking Water Only

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q* = .0119)
Adults 20-49	0.000836	9.94E-06
Adults 50-99	0.000826	9.83E-06
Female 13-49	0.000833	9.91E-06

Results of Assessments Based on an EDWC of 20 ppb

Food and Drinking Water

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q* = .0119)
Adults 20-49	0.000477	5.68E-06
Adults 50-99	0.000452	5.38E-06
Female 13-49	0.000448	5.33E-06

Drinking Water Only

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q* = .0119)
Adults 20-49	0.000418	4.97E-06
Adults 50-99	0.000413	4.92E-06
Female 13-49	0.000416	4.95E-06

Results of Assessment for Food Only: No Drinking Water EDWC Included

US EPA
DEEM-FCID Chronic analysis for PYMETROZINE
Residue file name: C:\Users\ddotson\Documents\DEEM Version 3.16\Pymetrozine 2017
DRA\PymetrozineChronicFoodOnly.R08
Ver. 3.16, 03-08-d
NHANES 2003-2008 2-day
Adjustment factor #2 used.
Analysis Date 12-09-2017/10:07:53 Residue file dated: 12-09-2017/09:55:39
Q* = 0.0119

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Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q*= .0119)
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Adults 20-49	0.000060	7.12E-07
Adults 50-99	0.000039	4.68E-07
Female 13-49	0.000032	3.77E-07
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Attachment 11: Pymetrozine Screening Level Usage Analysis (SLUA)

Pymetrozine (101103)
Screening Level Usage Analysis (SLUA)
April 22, 2016

What is a Screening Level Usage Analysis (SLUA)?

- Available estimates of pesticide usage data for a particular active ingredient that is used on **agricultural** crops in the United States.
- Pesticide usage data obtained from various sources. The data are then merged, averaged, and rounded so that the presented information is not proprietary, business confidential, or trade secret.

What does it contain?

- Pesticide usage data for a **single** active ingredient only.
- Agricultural use sites (crops) that the pesticide is *reported* to be used on.
- Available pesticide usage information from U.S. states that produce 80% or more of a crop, in most cases, or less than 80%, in rare cases, depending on the scope of the survey and available resources.
- Annual percent of crop treated (**average & maximum**) for each agricultural crop.
- Average annual pounds of the pesticide applied for each agricultural crop (i.e., for the states surveyed, not for the entire United States).

What assumptions can I make about the reported data?

- **Average pounds of active ingredient applied** - Values are calculated by merging pesticide usage data sources together; averaging across all observations, then rounding. *Note: If the estimated value is less than 500, then that value is labeled <500. Estimated values between 500 & <1,000,000 are rounded to 1 significant digit. Estimated values of 1,000,000 or greater are rounded to 2 significant digits.)*
- **Average percent of crop treated** - Values are calculated by merging data sources together; averaging by year, averaging across all years, & rounding to the nearest multiple of 5. *Note: If the estimated value is less than 2.5, then the value is labeled <2.5. If the estimated value is less than 1, then the value is labeled <1.*
- **Maximum percent of crop treated** - Value is the single maximum value reported across all data sources, across all years, & rounded up to the nearest multiple of 5. *Note: If the estimated value is less than 2.5, then the value is labeled <2.5.*

What are the data sources used?

- **USDA-NASS** (United States Department of Agriculture's National Agricultural Statistics Service) – pesticide usage data from 2005 to 2014.
- **Private Pesticide Market Research** – pesticide usage data from 2005 to 2014.
- **California Department of Pesticide Regulation (DPR) Pesticide Use Reporting (PUR)** data for 2005 to 2013.

What are the limitations to the data?

- Additional registered uses may exist but are not included because the available surveys do not report usage (e.g., small acreage crops).
- Lack of reported usage data for the pesticide on a crop **does not imply** zero usage.

- Usage data on a particular site may be noted in data sources, but **not quantified**. In these instances, the site would not be reported in the SLUA.
- Non-agricultural use sites (e.g., turf, post-harvest, mosquito control, etc.) are not reported in the SLUA. A separate request must be made to receive these estimates.
- Some sites show some use, even though they are not on the label. This usage could be due to various factors, including, but not limited to Section 18 requests, use of existing stocks of a cancelled chemical, data collection errors, and experimental use permits (EUPs).

April 22, 2016
Screening Level Estimates of Agricultural Uses of Pymetrozine (101103)
Sorted Alphabetically – Reporting Time: 2005-2014

			Percent Crop Treated	
Crop		Average Lbs. A.I. Applied per Year	Average	Maximum
1	Asparagus	<500	5	10
2	Broccoli	<500	<2.5	10
3	Brussels Sprouts*	<500	15	20
4	Cabbage	<500	5	15
5	Cantaloupes	<500	5	20
6	Cauliflower	<500	5	10
7	Celery	1,000	20	35
8	Chicory*+	<500	5	10
9	Cucumbers	<500	<2.5	5
10	Lettuce	1,000	5	15
11	Pecans	1,000	<2.5	5
12	Peppers	<500	5	25
13	Potatoes	8,000	5	15
14	Pumpkins	<500	<2.5	10
15	Spinach	<500	<2.5	<2.5
16	Squash	<500	<2.5	5
17	Tobacco	<500	<1	<2.5
18	Tomatoes	1,000	5	20
19	Watermelons	<500	<2.5	10

All numbers rounded.

<500: less than 500 pounds of active ingredients.

<2.5: less than 2.5 percent of crop is treated.

<1: less than 1 percent of crop is treated.

* Based on CA DPR data only (80% or more of U.S. acres grown are in California).

+ : Chicory not known to be listed on active end use product registrations or as Section 18 emergency exemptions when this report was run.

SLUA data sources include:

USDA-NASS (United States Department of Agriculture's National Agricultural Statistics Service)

Private Market Research Data

California DPR (Department of Pesticide Regulation)

These results reflect amalgamated data developed by the Agency and are releasable to the public.